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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1968

No. [redacted] 86

AMP INCORPORATED, *Petitioner*,

v.

WILBUR J. COHEN, Secretary of Health, Education and Welfare; and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents*.

## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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AMP Incorporated prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit, entered in the above-entitled case on February 13, 1968.

### CITATIONS TO OPINIONS BELOW

The opinion of the District Court (R. 277-292), printed in Appendix B hereto, *infra*, p. 2a, is reported in 275 F. Supp. 410 (S.D.N.Y. 1967). The opinion of the Circuit Court of Appeals (R. 297-310), printed in Appendix B hereto, *infra*, p. 13a, is reported in 389 F. 2d 825 (2d Cir. 1968).

## JURISDICTION

The judgment of the United States Court of Appeals for the Second Circuit was entered on February 13, 1968. R. 311; p. 26a, *infra*. The jurisdiction of this court is invoked under 28 U.S.C. § 1254(1).

## QUESTION PRESENTED

The "drug" definition in the Federal Food, Drug, & Cosmetic Act specifies that the term "does not include devices". "Drugs" which are "new drugs" are subject to governmental preclearance; "devices" are not.

The question presented is whether the concept of "instruments, apparatus, and contrivances" as contained in the "device" definition of the Act is limited in its application to only such devices as Congress expressly exemplified at the time of passage of the Act, rather than to all instruments, apparatus, and contrivances intended for the uses set forth in the definition.

## STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U.S.C. § 301, *et seq.*, provides in part:

> Sec. 201[321]. For the purposes of this Act—
>
> * * * *
>
> (g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of

the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

* * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, * * *; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Sec. 505[355]. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been

made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

* * *

## STATEMENT

Petitioner is the manufacturer of two types of surgical ligatures, which are implements for tying severed blood vessels. The first consists of a plastic pliers-like holder (called a hemostat) to which is attached a strand of nylon suture material extending in a loop beyond the hemostat. The second is a narrow hollow plastic rod to which is attached a similar strand. By manipulating the hemostat or rod, a tiny locking disc strung on the suture strand can be made to slide along the strand, reducing the aperture of the loop in much the same manner as a hangman's knot tightens a noose. In surgical procedures the loop is placed so as to encircle a severed blood vessel and, when pulled tight, constricts the vessel, thereby stopping the flow of blood therefrom. Samples of petitioner's products are appended hereto.

The Food, Drug, and Cosmetic Act of 1938 prescribes distinctive regulatory schemes for "drugs" and for "devices". The term "drug" is defined to include, *inter alia,* (A) "articles" recognized in official compendia such as the U.S. Pharmacopoeia, (B) "articles" intended for certain specified uses, and (C) "articles

* * * intended to affect the structure or any function of the body" [21 U.S.C. 321(g)(1)(A)-(C)]. Drugs not generally recognized as safe and effective for conditions recommended in their labeling are classified as "new drugs" and must be approved by the Food and Drug Administration before being marketed in interstate commerce (21 U.S.C. § 355). "Devices" are defined as "instruments, apparatus, and contrivances" intended, *inter alia,* "to affect the structure or any function of the body" [21 U.S.C. § 321(h)(2)]. The statute explicitly provides that the category "drug * * * does not include devices or their components, parts, or accessories" [21 U.S.C. § 321(g)(1)(D)]. There is no provision for premarket approval of "new devices"; if a product is not a "drug" within the meaning of the statute no premarket approval is required.

In 1966 petitioner requested the opinion of the Food and Drug Administration (FDA) as to whether its two ligature products were drugs, new drugs, or devices. Some weeks later the FDA advised petitioner that the products were regarded as "new drugs". After some further exchanges of correspondence in which petitioner asserted its disagreement with the FDA's view and the FDA adhered to its position, with the imminent threat of seizure, petitioner initiated this declaratory judgment action under 28 U.S.C. § 2201 in the district court, seeking an (A) adjudication that the products in question were devices rather than drugs (new or otherwise) and (B) an injunction against enforcement of the drug and new-drug provisions of the Act against petitioner or its ligature products. The jurisdiction of the district court was based on 28 U.S.C. §§ 1331(a) and 1337.

*The decision of the district court.* Characterizing petitioner's products as fundamentally "sutures", the district court found it "clear that the products fit into the broad definition of 'articles' ", and "[l]ess clear * * * whether such items could fit within the definition of 'devices' " as "instruments, apparatus, and contrivances" (275 F. Supp. at 414, p. 8a *infra*). Holding, however, despite the view of both petitioner and the Government to the contrary that " 'the categories * * * "drug" and "device" should not be defined as mutually exclusive' " (*ibid.*), the court concluded, in light of the premarket clearance procedure applicable to "new drugs", that, even if petitioner's ligatures were within the statutory definition of "device" as well as within the "drug" definition, "[t]he public will be better protected by classifying plaintiff's products as drugs rather than [merely?] as devices so that proper testing, controlled by the government, can be pursued" (*ibid.*).

*The decision of the court of appeals.* On petitioner's appeal the decision of the district court was affirmed. The court of appeals noted (389 F. 2d at 829, p. 21a *infra*) that at the time the categories "drug" and "device" were first separated by the Senate Commerce Committee during its drafting of the Federal Food, Drug, and Cosmetic Act, there was no difference between the regulatory schemes applicable to the two types of products; the "new drug" provisions of the Act had not yet been developed. Attributing Congress' differentiation between "drugs" and "devices" to lack of "attention to the fact that [with the inclusion of premarket clearance procedures for new drugs] the distinction * * * had thus for the first time become important" (*ibid.*), the court declined to "suppose that when Congress incorporated the 'new drug' bills * * *

into an Act which contained an extremely broad definition of the word 'drug', it intended that the operation of those provisions should be restricted to products commonly called 'drugs', and that products such as ligatures, which might present the very dangers the provisions were designed to meet, should be excluded" (*id.* at 830).

The court therefore concluded that "[t]he exclusionary classification 'devices' should * * * be limited to such things as Congress expressly intended it to cover" (the court did not, however, identify any particular products as within this limited class); that ligatures were not within that limited class; and that as "[t]he language of [the 'drug' definition] plainly permits calling [petitioner's] nylon thread and disk, in their intended use, 'drugs', * * * that is their appropriate classification" (*ibid.*).

## REASONS FOR GRANTING THE WRIT

The effect of the decision below is to impose upon virtually the entire medical device industry an elaborate premarketing clearance scheme actually designed only for drugs, which no one—not even the Government—has ever contended was or even should be applicable to devices. The premise upon which the court of appeals proceeded is in conflict, moreover, with the holding of the Sixth Circuit in a recent similar controversy. Whether the Federal Food, Drug, and Cosmetic Act as presently written is to be thus construed to bring the device industry under the existing premarket clearance scheme, hitherto thought applicable only to drugs, is a question of manifest importance which should not be left to the court of appeals but rather decided only by this Court.

1. All products in interstate commerce "intended to affect the structure or any function of the body" are regulated by the Federal Food, Drug, and Cosmetic Act. Throughout the Act, however, runs a clearcut division of such products into the category "drug" on the one hand and "device" on the other. The regulatory scheme applicable to each category is distinctive and sharply different from the other. The principal difference is the applicability of a complex premarket clearance procedure to "drugs" which are not "generally recognized as safe and effective". Without prior approval from the Food and Drug Administration, which can be obtained only by demonstrating safety and efficacy, no such drug can lawfully be marketed in interstate commerce. In contrast, there is no such requirement for "devices", which can be marketed without any prior Government approval and are subject to regulatory action only *after* being marketed if "adulterated" or "misbranded" (e.g. falsely or misleadingly labeled as to safety or efficacy).

The yardstick for determining which of these two disparate regulatory schemes is applicable to a particular product is the definition section of the Act (21 U.S.C. § 321). A product which is "intended to affect the structure or any function of the body" may be either a "drug" or a "device". Products which are "instruments, apparatus, and contrivances" are "devices"; "articles" are "drugs". While "articles" would seem logically to include "instruments, apparatus, and contrivances", the Act expressly declares that "the term 'drug' * * * does not include devices * * *".

The court of appeals held that, because it would be desirable in its view of the public interest to subject

as many products as possible to the premarket clearance requirements applicable to "new drugs", the statutory definition of "device" should be construed as narrowly as possible to include only "*such things as Congress expressly intended it to cover*" (emphasis added). Since the definition of "drug" and "device" are identical except for the distinction between "instruments, apparatus, and contrivances" and other "articles", the effect of the decision is to make "drugs" of all but a few products previously thought by all to be "devices".

This is a highly novel construction, never before advanced. Its effect would be to bring within the "new drug" premarket clearance scheme virtually an entire industry—products heretofore always regarded as "instruments, apparatus, and contrivances" and thus subject only to the regulatory scheme laid down by Congress for "devices".

The novelty of the court of appeals' position is demonstrated by the recent efforts of the Food and Drug Administration to obtain new legislation in this general direction [H.R. 10726, 90th Cong., 1st Sess. (1967); see also, H.R. 11582, 87th Cong., 1st Sess. (1961)]. The immense impact of the decision below—that drug classification has been in effect for all "instruments, apparatus, and contrivances" except for those few that were "expressly intended" by Congress 30 years ago to be devices—is illustrated by the statements of the FDA in support of its legislative proposals for the enactment of such "new device" legislation:

a) In a "Fact Sheet" released by the FDA describing its proposed "Medical Device Safety Act of 1967" (reprinted as Appendix D *infra*), the agency recognized that "revolutionary advances in the development

of medical devices" since enactment of the Federal Food, Drug, and Cosmetic Act have produced "a broad array of devices that are new, not only in purpose and usefulness, but often in the very materials used in their manufacture". The FDA states unequivocally that this recently-developed industry, which includes "[s]urgical implants, contact lenses, artificial kidneys, and nylon arteries" is outside the coverage of existing premarket clearance law: "No Federal law requires advanced proof of safety, reliability, and effectiveness before a device reaches the market". The agency urges the introduction of "[a]ppropriate legislation * * * now to close this gap".

All this is changed by the decision of the court of appeals in the present case. The entire industry which has sprung from the "revolutionary advances" of 30 years referred to by the FDA, as well as all traditional medical devices not "expressly intended" to be exempt, is now subject to premarket clearance under the decision below. Nor does the court of appeals' decision simply apply the general concept of premarket clearance to all but the few "exempt" devices; the particular regulatory scheme applicable to "new drugs" is now applicable to most devices as well. Whether this is the scheme best fitted to the device industry might well be debated; the Food and Drug Administration proposal to Congress is for a far different and less complex scheme which took into account numerous considerations peculiar to the device industry. Preclearance was sought not for all devices but only where in the view of the FDA preclearance "was plainly needed" (Letter from the FDA to Representative Jarman, Appendix E *infra*). But under the decision below, in contrast, the scheme applicable to virtually

all devices is the "new drug" scheme, in its entirety and without modification or exception.

b) The broad scope of the court of appeals' decision is apparent from the inclusive nature of the list of products identified as "devices" in FDA's letter to Representative Jarman. Noting that "the definition of 'device' in the Federal Food, Drug, and Cosmetic Act is an extremely broad one" (p. 37a *infra*), the FDA listed the following "devices" for which no premarket clearance but merely compliance with Federal standards should be required:

infant incubators
sterilizer controls
oxygen tents
resuscitators and defibrillators
anesthetic equipment
therapeutic ultra-sound devices
diathermy machines
electrosurgical units and accessories
low volt generators
conductivity testers
oscillograph recorders
surgical sutures (USP)
gall bladder instruments
thoracic instruments
brain instruments
eye instruments (tonometer)
ear, nose and throat instruments
(audiometer, tracheotomy tubes)
genito-urinary instruments
ob-gynecology instruments
implant materials
cardiac catheters
and metal prostheses.

Other "devices" for which the FDA has proposed neither premarket clearance nor standards regulation are:

sterilizer controls
oxygen tents
syringes
anesthesia instruments
hemostatic forceps
operating retractors
surgical needles
surgical sutures (USP)
certain eye instruments
certain ear, nose and throat instruments
sponges
bandages
and rehabilitation equipment.

All these products, which in the FDA's view are "intended to affect the structure or any function of the body", would under the decision below be "drugs" rather than "devices" unless "expressly intended" by Congress in 1938 to be exempt from premarket clearance, and, unless generally recognized as safe and effective, would require advance approval by the FDA under the "new drug" provisions before being marketed in interstate commerce. If the Federal Food, Drug, and Cosmetic Act is now to be judicially interpreted to so require, the decision to do so should be made by this Court and no other.

2. Nor can the decision below be reconciled with the recent holding of the Court of Appeals for the Sixth Circuit in *United States* v. *An Article of Drug* * * * *Bacto-Unidisk* * * *, No. 17592, 6th Cir., March 29, 1968 (unreported) (Appendix C *infra*), where the Government's effort to apply the "drug" definition in a similar literalistic manner was firmly rejected. The product there involved was a cardboard disc impreg-

nated at different spots with different antibiotics, to which a patient's specimen might be applied to determine his sensitivity to the particular antibiotic. The Federal Food, Drug, and Cosmetic Act contains, in addition to the definition discussed above, a provision defining "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" [21 U.S.C. § 321(g)(1)(B)].

Despite the Government's argument that the disc was an "article" intended for such use and therefore a "drug" within the meaning of the Act, the Sixth Circuit adopted the finding of the district court—contrary to the decision in the present case—that there was no basis for concluding that the definition of "drug" in the Act "was intended by Congress to extend beyond the meaning of that term in medical science, * * *". The "generally accepted view among physicians" was held to exclude products such as sensitivity discs from the category of "drugs", and the district court's dismissal of a seizure and condemnation suit against a quantity of the discs was affirmed.

The conflict between the Second and Sixth Circuits is apparent. If the definition of "drug" in the Federal Food, Drug, and Cosmetic Act is to be read as literally and broadly as possible, as the Second Circuit in the case at bar would have it, products such as sensitivity discs would plainly be within the regulatory scheme applicable to drugs. If, on the other hand, the definitions are to be read on the premise relied upon by the Sixth Circuit in *Bacto-Unidisk*—that Congress intended to apply the "drug" regulatory scheme to only those products considered "drugs" by medical

science—then ligature products like those of petitioner here would clearly be outside the "drug" category.[1] Consistent and predictable administration of the Federal Food, Drug, and Cosmetic Act requires this Court to resolve the fundamental conflict between the courts of appeals over the proper criteria for determining when the "drug" provisions of the Act apply.

## CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

MARSHALL M. HOLCOMBE
*Counsel for Petitioner*

May 10, 1968.

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[1] Although the court below apparently held that "sutures" have traditionally been considered "drugs" and were therefore not "expressly intended" to be excluded from that category (389 F. 2d at 830, pp. 22a-23a *infra*), the legislative history of the Federal Food, Drug, & Cosmetic Act clearly demonstrates precisely the contrary. (Hearings Before the Senate Commerce Committee on S. 2800, 73d Cong., 2d Sess., p. 516 (1934); Hearings Before the House Commerce Committee on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5, 74th Cong., 1st Sess., pp. 319-20 (1935); see also Hearings Before the Senate Commerce Committee on S. 1944, 73d Cong., 2d Sess., p. 15 (1933). The letter from the FDA to Rep. Jarman, discussed above, listed "surgical sutures" as devices for which standards would suffice, and would have reserved premarket clearance for only those sutures "with previously unknown medical applications".